

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1-27. (Cancelled)

28. (Currently Amended) A method for determination of concentration of one or more analytes in a test sample or an aliquot of a test sample of a complex biological fluid, comprising characterized by

a) mixing the ~~said sample~~ or aliquot of the ~~said sample~~ with one single reagent, ~~such as a solid, a solution or premixed solution~~, wherein

said reagent ~~being~~is provided in one single container or compartment of a container, and no other reagent is added during the performance of said method, and

said reagent comprises at least one type of binding molecule with specific affinity for one or more of ~~the said~~ analytes, and

said reagent ~~furthermore~~ comprises fluorescent moieties covalently linked to the ~~said~~ binding molecules forming a binding pair, wherein the ~~said~~ binding pair comprises a binding pair selected from the group consisting of:

(i) an aptamer or another synthetic binder with a molecular weight below 5,000 complexed to fluorescent moieties or fluorescent analogues of said analyte, fragments of said analyte, or derivatives of said analyte, wherein this mixing provides an analyte-binding molecule-fluorescent moiety complex of changed size, or the said binding pair being

(ii) a peptide binder or peptidic synthetic binder with a molecular weight below 5,000 complexed with fluorescent moieties, wherein this mixing provides an analyte-binding molecule-fluorescent moiety complex of changed size, or the said binding pair comprises

(iii) an antibody or an immunoactive antibody fraction complexed to fluorescent analogues of or fluorescent fragments of, or fluorescent derivatives of said analyte or analytes wherein this mixing provides a competitive reaction with resulting changed fluorescence, and;

b) ~~said mixing resulting in a mixture which is being irradiated~~ irradiating a resulting mixture with polarized light to permit~~which permits~~ the excitation of said fluorescent molecules, and

- c) measuring the polarization of the emitted light, and
- d) calculating the concentration or concentrations of said analyte or analytes wherein said analyte or analytes is not an antibody.

29. (Currently Amended) A method according to claim 28,
~~characterized in that~~ wherein the test sample or the aliquot of a test sample is whole blood or anti-coagulated whole blood.

30. (Currently Amended) A method according to claim 28,
~~characterized by~~ comprising using a reagent for each analyte comprising immunocomplexes between

- a) an antibody or an immunoactive fragment of an antibody with specific affinity for said analyte or analytes, and
- b) at least one of fluorescent analogues of said analyte or analytes, ~~or~~ fluorescent fragments of said analyte or analytes, or fluorescent derivatives of said analyte or analytes.

31. (Currently Amended) A method according to claim 28,
~~characterized by~~ comprising using a reagent for each analyte comprising complexes between

- a) an aptamer or another synthetic binder with a specific affinity for said analyte, and
- b) at least one of fluorescent analogues of said analyte or analytes, ~~or~~ fluorescent fragments of said analyte or analytes, or fluorescent derivatives of said analyte or analytes..

32. (Currently Amended) A method according to claim 28,
~~characterized by~~ comprising using a reagent comprising binding molecules with specific affinity for one or more of the ~~said~~ analytes and with fluorescent moieties with absorption maximum between 600 nm and 1000 nm, ~~preferably above 620 nm,~~ covalently linked to said binding molecules, ~~and said binding molecules being either a peptide or being synthetic binders,~~ optionally being identified by ~~combinatory chemistry techniques or phage display or nucleic acid selection technology.~~

33. (Currently Amended) A method according to claim 32,
~~characterized by the use of a~~wherein the reagent comprising comprises peptides or derivatives of
peptides containing an amino acid sequence at least one of Ala-Arg-Asn-Arg-Asn or Ala-Arg-
Asn-Gly-Asn ~~for and said reagent is used for the~~ quantitation of C-reactive protein.

34. (Currently Amended) A method according to claim 28,
~~characterized by comprising~~ using a reagent comprising at least one of (i) fluorescent binding
molecules with specific affinity for one analyte, or ~~comprising(ii)~~ fluorescent analogues of, or
fluorescent fragments of, or fluorescent derivatives of one analyte only.

35. (Currently Amended) A method according to claim 28,
~~characterized by comprising the use~~using of a reagent comprising different fluorescent moieties
covalently bound to different binding molecules with different specific affinities.

36. (Currently Amended) A method according to claim 28,
~~characterized by comprising the use~~using of a reagent comprising one or more peptides or
derivatives of peptides with specific binding affinity for an analyte, said binding peptides having
a fluorescent residue covalently linked, ~~and being constituted by~~ wherein the peptide is less than
30 amino acids.

37. (Currently Amended) A method according to claim 36,
~~characterized in that~~ wherein the binding peptide is ~~constituted by~~ less than 20 amino acids.

38. (Currently Amended) A method according to claim 37,
~~characterized in that~~ wherein the binding peptide is ~~constituted by~~ less than 15 amino acids.

39. (Currently Amended) A method according to claim 28,
~~characterized by comprising the use~~using of a reagent with fluorescent residues with maximum
coefficient of absorption at a wavelength above 640 nm.

40. (Currently Amended) A method according to claim 28, ~~characterized by comprising the use~~using of a reagent comprising at least one of cell lysing substances, ~~or~~ anti-coagulants, or detergents.

41. (Currently Amended) A method according to claim 28, ~~characterized by comprising the use~~using of a reagent comprising one or more fluorescent moieties selected from the group consisting of fluoresceine, Texas Red, Cy5, ~~other Cy Dye FluorLink substances, other Cyanin derivatives, Rhodamin, Methyl Rhodamin, Biodypi 630/650-X/MeOH, Biodypi 650/655-X/MeOH, Biodypi FL/MeOH, Biodypi R6G/MeOH, Biodypi TMR-X/MeOH, Biodypi TR-X/MeOH or other substances from the Biodypi group of substances, Alexa Fluor Dyes of different wavelengths, Ruthenium ligand complexes, lanthanoid elements such as Europium, Samarium or Terbium complex bound to a chelating ligand like~~ comprising DTPA, EDTA or N1.

42. (Currently Amended) A method according to claim 28, ~~characterised by that~~wherein the polarisation of the emitted light is measured as a function of time, either as a continuous kinetic reading or a reading of the change in the polarisation of the emitted light between two or more time points, or as a measurement of the polarisation of the emitted light after a defined point of time.

43. (Currently Amended) A method according to claim 28, ~~characterised by that~~wherein sample material or aliquot of the sample material ~~is constituted by a~~comprises biological material, or a dilution or an extract or being dissolved from or being filtrated from the said biological material.

44. (Currently Amended) A method according to claim 28, ~~characterised by that~~wherein sample material or aliquot of the sample material ~~is constituted by a~~comprises at least one of blood, ~~or~~ blood serum, ~~or~~ blood plasma, ~~or~~ blood cells, ~~or~~ lysate from blood or blood cells, ~~or~~ urine, ~~or~~ cerebrospinal fluid, ~~or~~ tear liquid, ~~or~~ sputum, ~~or~~ semen, ~~or~~ plasma, ~~or~~ semen or material aspirated from the gastro-intestinal tract or feces, ~~or~~ extract or filtrate from the suspension of feces, ~~or~~ plant material or extracts thereof, or dissolved plant material or filtrate thereof.

45. (Currently Amended) A method according to claim 28, ~~characterized by comprising the~~ using of standards or calibrators comprising known concentrations of the analyte or the analytes, ~~and furthermore~~ wherein the concentration or concentrations of said analyte or analytes in unknown samples is calculated by interpolation of the values obtained from the unknown samples on the standard curve obtained from said known standards or calibrators.

46. (Currently Amended) A method according to claim 28, ~~characterized by comprising the~~ using of a standard curve stored in an artificial memory, ~~optionally connected to a the~~ fluorescent polarisation instrument in use.

47. (Currently Amended) A method according to claim 28, ~~characterized by comprising the~~ using of temperature correction algorithms, either generated empirically or theoretically, to compensate for differences in fluorescence polarisation caused by differences in temperature at different time of measurements ~~of between~~ standards and unknown samples, ~~or between~~ standards, or between unknown samples.

48. (Currently Amended) A method according to claims 28, ~~characterised by being wherein~~ the reagent is provided in concentrated or dry form, the reagent is to be diluted or reconstituted before use, and the said reagent is being provided divided between different compartments for combination into one reagent prior to use.

49. (Currently Amended) A method according to claim 28, ~~characterised in that~~ wherein said reagent comprises at least one type of binding molecule with specific affinity for one or more of the ~~said~~ analytes, and said reagent ~~furthermore~~ comprises fluorescent moieties covalently linked to the ~~said~~ binding molecules or fluorescent analogues of said analyte or analytes, ~~or~~ fluorescent fragments of said analyte or analytes, or fluorescent derivatives of said analyte or analytes.

50. (Currently Amended) A ~~method reagent~~ according to claim 49, ~~characterised in that~~ wherein the reagent comprises complexes between a) an antibody or an immunoactive fragment of at least one of an antibody, ~~or~~ an aptamer, or a synthetic binder with specific affinity for at

least one analyte and b) at least one of fluorescent analogues of said analyte or analytes, or fluorescent fragments of said analyte or analytes, or fluorescent derivatives of said analyte or analytes.

51. (Currently Amended) A ~~method reagent~~ according to claim 49, ~~characterised in~~ comprising binding molecules with specific affinity for one or more of the said analytes and ~~optionally~~ with fluorescent moieties with absorption maximum between 600 nm and 1000 nm, ~~preferably exceeding 620 nm, more preferably exceeding 640 nm,~~ covalently linked to the said binding molecules, and said binding molecules being either of peptide or aptamer composition or being synthetic binders, ~~optionally being identified by combinatorial chemistry techniques or phage display or nucleic acid selection technology.~~

52. (Currently Amended) A ~~method reagent~~ according to claim 49, ~~characterised in that~~ wherein being an assay reagent ~~comprising~~ comprises peptide binders or binders of derivatives of peptides, including fluorescent derivatives of said binders, containing at least one of the following amino acid sequences: Ala-Arg-Asn-Arg-Asn and/or Ala-Arg-Asn-Gly-Asn.

53. (Currently Amended) ~~Use of the~~ The method according to claim 28 ~~comprising to~~ determineing concentrations of ~~clinically related~~ biologically relevant substances in samples of biological material from living organisms in biological need of said biologically relevant substances thereof.

54. (Currently Amended) Kit for determination of concentration of one or more analytes in a test sample or an aliquot of a test sample of complex biological fluid containing an analyte(s), ~~characterized in~~ comprising one or more containers, wherein the container(s) or compartment of the container(s) contains one single reagent, ~~preferably in the fluidal state and according to claim 48, and~~ wherein the reagent comprises at least one type of binding molecule with specific affinity for the analyte(s), and
said reagent further comprises fluorescent moieties covalently linked to the binding molecules forming a binding pair, wherein the binding pair comprises a binding pair selected from the group consisting of:

(i) an aptamer or other synthetic binder with a molecular weight below 5,000 complexed to fluorescent moieties or fluorescent analogues of said analyte, fragments of said analyte, or derivatives of said analyte, or

(ii) a peptide binder or peptidic synthetic binder with a molecular weight below 5,000 complexed with fluorescent moieties, or

(iii) an antibody or an immunoactive antibody fraction complexed to fluorescent analogues of or fluorescent fragments of, or fluorescent derivatives of said analyte or analytes, comprises one or more a fluorescence-labelled specific binding molecules towards the analyte(s) to be measured, or a fluorescence-labelled analogue or a fluorescent fragment or a fluorescent derivative of said analyte(s), as well as and a device for obtaining the exact volume(s) of the complex biological fluid to be tested and that is needed in order to perform the method adequately.

55. (Currently Amended) Kit according to claim 54, ~~characterized in that~~wherein the reagent which is contained in atthe container or atthe compartment of a container, is formed to a ready-for-use reagent by mixing the content from different containers prior to₁ ~~or~~ immediately prior to₂ or in connection with₁ the execution of the analysis.